In the Supreme Court of the 13 1977 **United States**

MICHAEL RODAK, JR., CLERK

OCTOBER TERM, 1976

No. 76-798

A. H. ROBINS COMPANY, INC.,

Petitioner.

DEPARTMENT OF HEALTH OF THE STATE OF CALIFORNIA (formerly Department of Health Care Services of the Human Relations Agency, State of California), et al., Respondents.

Brief in Opposition to Petition for Writ of Certiorari

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TABLE OF CONTENTS

	*	Page
Opinio	n Below	. 1
Questi	on Presented	. 2
Statut	ory Provision Involved	. 2
Staten	nent of the Case	. 2
Reason	ns for Denying the Writ	. 6
I.	Welfare and Institutions Code Section 14053.5 Does Not Conflict with the Federal Robinson- Patman Act	
II.	Welfare and Institutions Code Section 14053.5 Does Not Conflict with Title XIX of the Social Security Act	1
III.	There Is No Basis for Further Court Pro- ceedings in This Action. If Robins Desires to Argue Further, Such Argument Should Be Di- rected to the Legislature	
Conclu	sion	. 11
Annen	dix A	

CITATIONS

CASES

Pag
Fairmont Creamery Co. v. Minnesota, 274 U.S. 1 (1927)
Mountain Timber Co. v. Washington, 243 U.S. 219 (1916)
A. H. Robins Co., Inc. v. Department of Health, State of California, 59 Cal.App.3d 903 (1976) (Ct. App. 1976)
Shell Oil Co. v. Younger, 1976-1 Trade Cases (CCH) ¶ 60,960 (N.D.Cal. June 11, 1976)
CITATIONS
Title XIX, Social Security Act, 42 U.S.C.:
§§ 1396 et seq
1396(a)(2)
1396a(30)
1396c
Cal. Welf. & Inst. Code:
§§ 14000 et seq
§ 14053.5

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VS

DEPARTMENT OF HEALTH OF THE STATE OF CALIFORNIA (formerly Department of Health Care Services of the Human Relations Agency, State of California), et al., Respondents.

Brief in Opposition to Petition for Writ of Certiorari

Respondent Department of Health of the State of California respectfully submits the following opposition to the petition for writ of certiorari filed by petitioner herein.

OPINION BELOW

The opinion sought to be reviewed is that of the Court of Appeal of the State of California, Third Appellate District: A. H. Robins Co., Inc. v. Department of Health, State of California, 59 Cal. App. 3d 903 (1976).

QUESTION PRESENTED

May the State of California be forced to purchase the drug products of A. H. Robins Co. even though the California Legislature has decided not to purchase the products of a manufacturer who does not make such products available on the same terms and conditions to all Medi-Cal drug providers?

STATUTORY PROVISION INVOLVED

California Welfare and Institutions Code section 14053.5, cited in full at 59 Cal.App.3d at 906 and included herein as Appendix A.

STATEMENT OF THE CASE

This case involves the interpretation of California Welfare and Institutions Code section 14053.5. This case does not involve the Robinson-Patman Act nor any other provision of federal law relating to the anti-trust field. Although petitioner continually represents to this court that the Court of Appeal decision prohibits Robins' marketing practices in California, and, thus, that California has contradicted federal anti-trust policy, the exact opposite is true. The decision below does not prohibit Robins' marketing practices and makes absolutely clear that Robins may continue its current practices and that such practices are not illegal in California. It simply holds that if Robins does continue to treat Medi-Cal drug providers in a discriminatory fashion, the state may refuse to purchase Robins' drug products. Robins has demonstrated no right to force the state to pay for Robins' products and, indeed, could not establish such a right.

Welfare and Institutions Code section 14053.5 is part of the state Medi-Cal program (Welf. & Inst. Code §§ 14000 et seq.). The Medi-Cal program (known nationally as Medi-Caid) was enacted by the California Legislature in 1966 in order to establish a program of basic and extended health care services for recipients of public assistance and medically indigent persons and, by meeting the requirements of federal law, to qualify California for the receipt of federal funds made available under Title XIX of the Social Security Act (42 U.S.C. §§ 1396 et seq.). Since California has an approved plan and does qualify for federal funding pursuant to Title XIX, the costs of the Medi-Cal program are shared between the state and the federal government (42 U.S.C. § 1396(a)(2)).

Health care services made available through the Medi-Cal program include the provision of prescribed drugs. Welfare and Institutions Code section 14053.5, effective January 1, 1969, relates to the types of prescription drugs for which the state will allow payment pursuant to the program. That section provides in part:

"For the purposes of the Medi-Cal Act, the terms 'prescriped drug' and 'prescription drug' shall not include any drug which, because of differing prices charged by the manufacturer on a discriminatory basis or discriminatory refusal to sell by the manufacturer, or both, is not available on the same terms and conditions to all providers of prescription services, or any drug which is found to be overpriced in comparison to another drug which has an equivalent therapeutic effect, unless the director determines that the drug is vital to the program and no acceptable substitute is available."

The enactment of Welfare and Institutions Code section 14053.5 was the ultimate result of the legislative concern with higher Medi-Cal drug costs.

It was undisputed that Robins' marketing practices do not make the subject prescription drugs available to all providers on the same terms and conditions. Robins sells directly to pharmacies operated by nonprofit hospitals, and to federal, state, county, and city institutions (S.R. 30). Those providers can obtain Robins' drugs at a discount of 20% from Robins' list price, plus a 2% additional discount if payment is made within 30 days (S.R. 31). Robins does not sell directly to community retail drug stores, to private pharmacies operated by proprietary hospitals, or to private physicians, dentists, and surgeons (S.R. 30). Such providers must obtain Robins' drugs from wholesale drug concerns. Wholesale drug concerns obtain Robins' products at list price less a 16% discount, plus an additional 2% discount for cash.

It is also undisputed that in 1969 the State of California spent over \$67,000,000 for drug products under the Medi-Cal program, with over 90% of such drugs being purchased from community retail pharmacist providers—providers who pay the higher prices for Robins' drugs (S.R. 238; 59 Cal.App.3d at 908).

Subsequent to the effective date of Welfare and Institutions Code section 14053.5, the State Department of Health (formerly the Department of Health Care Services) determined that Robins' marketing practices were discriminatory in accordance with the terms of that section in that Robins' drugs were not available on the same terms and conditions to all providers of prescription drugs. Based on such findings, ten of Robins' drugs were ordered removed from the approved Medi-Cal formulary (drug list).

On August 26, 1969, Robins filed a complaint for declaratory and injunctive relief against the state challenging the constitutionality of the application of Welfare and Institutions Code section 14053.5 to Robins' business practices (S.R. 1).

As a result of that action, the parties stipulated to a hearing in accordance with the California Administrative Procedure Act. After hearing, the director of the Department of Health Care Services specifically found that Robins' marketing practices resulted in price discrimination between, and discriminatory refusal to sell to, providers of prescription services, and declared that Robins' drug products were, accordingly, not eligible for the California Medi-Cal Assistance Program (S.R. 29).

Thereafter, Robins filed a new action in order to obtain judicial review of the administrative decision. The two cases were consolidated and the trial court found that Robins' marketing practices did not violate the terms of section 14053.5 (S.R. 37, 38).

The California Court of Appeal for the Third Appellate District reversed the decision of the trial court and specifically concluded that Robins' marketing practices were discriminatory within the meaning of Welfare and Institutions Code section 14053.5 and that the state was empowered to remove Robins' drugs from the Medi-Cal formulary (S.R. 233; 59 Cal.App.3d 903).

Robins thereafter petitioned for hearing before the Supreme Court of the State of California (S.R. 249) and such hearing was denied on September 15, 1976 (S.R. 326).

Pursuant to Rule 21(1) of the Rules of the Supreme Court, the parties have stipulated and agreed to omit specified portions of the record as unnecessary for the determination of the petition. References to the Stipulated Record are referred to as "S.R."

REASONS FOR DENYING THE WRIT

I. Welfare and Institutions Code Section 14053.5 Does Not Conflict With The Federal Robinson-Patman Act

Robins has made several significant statements which demonstrate a basic misunderstanding of the meaning of the state's action and the effect of the decision by the Court of Appeal:

"... the decision of the California Court of Appeal, however, prohibits Robins from selling to nonprofit hospitals at a lower rate (20% off list price) as long as retail pharmacists and other proprietary providers can only procure Robins' products at a greater rate through wholesalers (16\%3\% off list price)... (Petition at 7.) (Emphasis added.)

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"The holding of the Court of Appeal requires Robins to sell its products at the same price to all providers ..." (Petition at 8.) (Emphasis added.)

Such argument by Robins is entirely incorrect. The decision of the Court of Appeal would not prohibit drug manufacturers from selling directly to nonprofit hospitals. Nor does the decision require any action by Robins. Robins is free to continue its marketing practices, discriminating between various categories of providers as its business considerations dictate. The state does not contend that such practices are illegal and does not prohibit them. It is simply that the Legislature has determined that the Medi-Cal program will not pay providers for Robins' drugs if Robins continues those discriminating marketing techniques. The Court of Appeal made this quite clear in its decision:

"The right of a manufacturer to sell its drug products does not guarantee either initial or continuing product eligibility of such drugs on the state's MediCal formulary list. Accordingly, we hold that if a drug manufacturer elects to make available its drug products to proprietary providers only at prices higher than available to nonprofit providers, the state may remove such drug products from its approved drug formulary list.

"Such action does not interfere with Robins' right to do business with any person, business or institution in the state; it simply means that a dispenser of such drugs to Medi-Cal patients may not look to the state for payment, as such drugs are not on the state's formulary list of approved drugs." 59 Cal.App.3d at 912, 913.

The crux of this case is not that Robins may disclose its business practices to the state to establish that they are reasonable methods of doing business and, thus, that Robins has a right to have its drugs on the approved Medi-Cal list. The point is that Robins has, for business purposes, created price differentials—Robins discriminates between classes of providers—and such marketing practices, said the court, disqualify a manufacturer's products from participation in the Medi-Cal program. As stated by the Court of Appeal:

"The question before us is not the right of Robins to sell its drug products at a discriminatory price free from a possible Robinson-Patman violation, but whether the State of California can remove from its approved drug formulary list certain Robins drug products because Robins has elected not to make available to all Medi-Cal prescription drug providers the same drugs at the same cost price." 59 Cal.App.3d at 912.

None of the authorities cited by Robins are applicable herein because the state has not banned Robins' pricing practices. For example, Robins cites Shell Oil Co. v. Younger, 1976-1 Trade Cases (CCH) ¶ 60,960, 69,246 (N.D.

Cal., June 11, 1976) as a case involving a California statute "strikingly similar to section 14053.5." But that case is not remotely related to the present case because in *Shell Oil* the statute in question provided for an outright prohibition against certain marketing and pricing practices (Petition at 14). But in this case the state has not prohibited Robins' marketing and pricing practices, rather it has only set forth circumstances under which it will itself do business.

The same is true in regard to the case of Fairmont Creamery Co. v. Minnesota, 274 U.S. 1 (1927) cited by Robins. That case involved a state statute which made it a crime for a person to engage in certain specified business practices. This case involves nothing of the sort. Robins is entirely free to continue its business practices.

The "Hobson's choice" asserted by Robins (Petition at 11-12) involves no federal anti-trust ramifications nor any constitutional questions. In fact, no such choice is involved. There is absolutely no evidence to indicate that section 14053.5 would require a manufacturer to either sell below its costs or lose customers to competitors. Standard Oil Co. v. Federal Trade Commission, 340 U.S. 231 (1951) cited by petitioner (Petition at 12), stands for the proposition that manufacturers cannot be compelled to choose between either runiously cutting their prices to all their customers to match the price offered to one, or refusing to meet their competition and then ruinously raising their prices to their remaining customers to cover increased unit costs. Respondent has no quarrel with that proposition.

Contrary to petitioner's assertions, no prohibition on Robins' marketing practices has been enacted by the state and no evidence exists to support petitioner's claims of disasterous business consequences. No conflict with federal anti-trust statutes can possibly exist.

II. Welfare and Institutions Code Section 14053.5 Does Not Conflict With Title XIX of The Social Security Act

Robins argues that the California Medi-Cal program must be in conformity with Title XIX of the Social Security Act (42 U.S.C. §§ 1396 et seq.). More specifically, Robins argues that Welfare and Institutions Code section 14053.5 must be in conformity with 42 U.S.C. section 1396a(30) which provides that payments for drugs under the state plan must not be "in excess of reasonable charges consistent with efficiency, economy, and quality of care." The state agrees that the state plan must be in conformity with the provisions of Title XIX and the state argues that section 14053.5 is entirely consistent with all applicable federal statutes and regulations.

First, it is noted that the Secretary of the Department of Health, Education and Welfare has never informed the State of California that Welfare and Institutions Code section 14053.5, or any of the state actions taken pursuant to that section, are out of conformity with Title XIX although it is the duty of the Secretary to notify states when they are not conforming with federal law (42 U.S.C. § 1396c).

Secondly, it is no answer to the action taken against Robins to say that, if the Court of Appeal decision is upheld, that Robins will simply eliminate the 20% discount given to nonprofit and governmental hospitals, or, that higher pharmaceutical costs will result for all hospital patients. Again, such assertions are entirely hypothetical and do not establish the effect of section 14053.5.

The California Legislature has sought to eliminate a cause of unjustifiable high drug costs. The Legislature can deal with future drug pricing problems if and when Robins and other drug manufacturers comply with the requirements

of section 14053.5 or cease to have the state purchase their drug products. There is simply no evidence to indicate any conflict with the Social Security Act and no conflict exists.

III. There Is No Basis for Further Court Proceedings in this Action. If Robins Desires to Argue Further, Such Argument Should Be Directed to the Legislature

Much of Robins' arguments are based upon the premise that the decision of the Court of Appeal will result in a "bad deal" for the state relating to drug costs in the Medi-Cal program.

The state officials charged with the duty and responsibility of maintaining the integrity of the Medi-Cal program have enforced the intent of the California Legislature as expressed in Welfare and Institutions Code section 14053.5. The Court of Appeal has upheld that enforcement in a reasoned decision. The California Supreme Court has denied a hearing.

"... The authority of the States to enact such laws as reasonably are deemed to be necessary to promote the health, safety, and general welfare of their people, carries with it a wide range of judgment and discretion as to what matters are of sufficiently general importance to be subjected to state regulation and administration." Mountain Timber Co. v. Washington, 243 U.S. 219, 238 (1916).

If Robins believes another solution should be sought, then the California Legislature is the place for further study and argument. There is simply no federal question of substance which requires a decision from this court.

11 CONCLUSION

For all of the above reasons, respondent respectfully submits that the petition for writ of certiorari should be denied.

Dated: January 10, 1977

Respectfully submitted,

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Appendix A

§ 14053.5

For the purposes of the Medi-Cal Act, the terms "prescribed drug" and "prescription drug" shall not include any drug which, because of differing prices charged by the manufacturer on a discriminatory basis or discriminatory refusal to sell by the manufacturer, or both, is not available on the same terms and conditions to all providers of prescription services, or any drug which is found to be overpriced in comparison to another drug which has an equivalent therapeutic effect, unless the director determines that the drug is vital to the program and no acceptable substitute is available.

Before the director determines that any drug has an equivalent therapeutic effect in comparison to another drug, or is vital to the program and no acceptable substitute is available, he must have received a report to that effect from the Medical Therapeutics and Drug Advisory Committee.

Nothing in this section shall be construed to apply to quantity or other nondiscriminatory discounts available on the same terms and conditions to all providers of prescription services, to sales by competitive bidding to federal, state or local governmental agencies, or to sales to wholesalers so long as the manufacturer does not require or induce the wholesalers to make the drug available other than on the same terms and conditions to all providers of prescription services.

This section shall not be construed to deny reimbursement to hospitals for prescribed drugs furnished to inpatients or, unless the regulations provide to the contrary, to registered outpatients.